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CTSI

CLINICAL & TRANSLATIONAL
SCIENCE INSTITUTE

ctsi.urmc.edu

CTSI Directors' Report



Nancy M. Bennett, MD, MS



Martin S. Zand, MD, PhD

This past year at the Clinical and Translational Science Institute (CTSI) has been a busy and exciting one for us! We completed our 10th year and just received renewal of funding for another 4 years from the National Institutes of Health (NIH). This renewed funding will allow us to continue offering programs that accelerate research so we can accomplish our goal of applying medical research to patient treatment and population health.

The CTSI was one of the first 12 institutions in the nation to receive a Clinical and Translation Science Award, which was established by the NIH in 2006. The award helps get new therapies to patients faster and aims to improve health nationwide and worldwide.

Since its inception in 2006, the CTSI has provided an infrastructure to support translational research – offering education, funding, and consultation on research-related issues for scientists at all stages of their careers. We are proud to note that researchers who won grants from the CTSI over the past 10 years subsequently secured almost \$58 million of further NIH funding.

In the next 4 years, the CTSI will continue that programming with renewed focus on applying innovative approaches and technologies to improving population health, which relies heavily on improving the University's capacity to analyze large, health care datasets, and encouraging scientists to work in teams.

Here is a brief highlight of our new initiatives over the next four years:

Community Engagement

URMC is one of the few academic medical centers in the country with community service as one its four core missions, and where our community actively helps to set the institutional research agenda and priorities. Key to this effort is the Center for Community Health (CCH), directed by Dr. Nancy Bennett, which provides the community engagement function of the CTSI. The CCH addresses health inequalities in our community and improves health through research, education, and service. It also hosts the Community Advisory Council (CAC), a diverse group of community leaders from across the region who partner with URMC and CTSI leadership, engaging in discussions of priorities and plans.

Population Health

Working in population health is about working with the community instead of on the community. Studying population health primarily concerns engaging patients and research participants. At the CTSI, patient and participant engagement often occurs directly – via the internet or a mobile application. This reduces some major barriers to participating in health care and related research so anyone can have a meaningful impact on the research process, from deciding which research questions to ask to how we attempt to find an answer.

Biomedical Informatics

We are doing research in an incredible time—our ability to generate and assemble data has far outstripped any single researcher's ability to analyze that data.

Population health solutions are often hidden in overwhelmingly large sets of health care data that confound traditional data handling systems.

Informatics, the study of information processing and engineering of new data handling systems, is a key to unlock some of these hidden solutions.

The CTSI Biomedical Informatics Team partners with the other informatics teams around the University of Rochester, including the new Goergen Institute for Data Science, to help researchers solve issues in health-care-related “big data”. The Team provides consultation and on-line tools to help researchers plan data collection, develop new data handling systems, manage data, and create simple ways of using pre-existing data.

Team Science

Medical research operates like an immense machine with many moving parts. Individual researchers, their ideas and data are but cogs in the wheel. Just as advancing a machine requires all of the cogs to work together, so medical research requires active coordination and collaboration among researchers. Biomedical research benefits when scientists from different backgrounds and different stages of the translational process (from working in molecules and cells to studying populations of people) work collaboratively to answer scientific questions.

The Trial Innovation Network is the latest team science development undertaken by the Clinical and Translational Science Award Program. The network leverages the expertise and resources of the 64 institutions funded by the CTSA to provide infrastructure for large, multi-site clinical trials. The network also serves as a national laboratory to study and refine how these clinical trials are conducted.

With this new round of funding, the CTSI is well poised to help advance the medical research machine by helping teams of researchers connect, learn, and get what they need to work faster and more efficiently.

Connect. Learn. Get what you need.

We encourage researchers in our community to come to us directly for assistance, and work with us to achieve our common goal of making this a healthier community.

Meliora!

What is CTSI?

The **Clinical and Translational Science Institute (CTSI)**, located in the Saunders Research Building at the URM, helps research teams work faster and better. Investigators, research coordinators and administrators will all find helpful programs and services at the CTSI.

Not sure what you need, or how to find it? Contact the Research Help Desk at researchhelp@urmc.rochester.edu for access to research-related services and expertise provided by the CTSI and many other organizations across the University.

Planning a new study? Get a roadmap of helpful services and required approvals.

Need space or experienced staff for your clinical study? The Clinical Research Center has skilled nursing and bionutrition staff, available in the conveniently-located inpatient unit in the main medical center building.

Find out what's happening! The CTSI Weekly Update starts your week off right with research-related news, events and funding opportunities. The CTSI Stories blog provides useful information on programs, services and more.

Interact! Follow the CTSI on Facebook, LinkedIn, Twitter and YouTube.

There is more! Check the CTSI website, ctsi.urmc.edu, for all the details.

\$19M Grant Will Help URMC Speed Medical Advances to Patients

The CTSI is supported in large part by a \$19 million grant from the National Institutes of Health (NIH) to continue programs that remove hurdles in the process of applying medical research to patient treatment and population health. The Clinical and Translational Science Award (CTSA) will support “bench-to-bedside” research and is the Medical Center’s third consecutive translational science award, bringing total funding from these grants to almost \$86 million.

“Ten years ago the University of Rochester was catapulted to the forefront of the National Institutes of Health’s initiative to reengineer our nation’s biomedical research enterprise,” said Joel Seligman, president and CEO of the University of Rochester. “This award marks another important milestone in our efforts to bring together the scientific talent, the resources, and the expertise necessary to advance medicine and improve health.”

“The University of Rochester is an anchor of innovation that has helped our community become a national leader in cutting-edge research,” said U.S. Representative Louise Slaughter. “I’m pleased that the university’s Clinical and Translational Science Institute will be receiving more than \$19 million over the next four years to keep its teams of ground-breaking researchers on the job. This is a very substantial federal investment that will help the university continue translating the latest research into lifesaving treatment.”

“Translational medicine represents the bridge between new scientific discoveries and better health and the UR CTSI will continue to drive both research growth and improvements in patient care both in Rochester and



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beyond,” said Mark Taubman, M.D., CEO of the University of Rochester Medical Center and dean of the School of Medicine and Dentistry. “This new grant is a testament to the Medical Center’s national leadership in this field and our commitment to harness biomedical research to improve health.”

“With this \$19 million federal investment, we are putting the University of Rochester on the frontline of our nation’s drive to cure disease,” said U.S. Senator Charles Schumer. “We will take the discoveries made in Rochester’s Clinical and Translational Science Insti-

tute from the laboratory and turn them into actual treatments for patients that will save lives and improve quality of life. Starting a decade ago the UR CTSI was one of only a dozen institutions to be selected for a federal Clinical and Translational Science Award, and now this new funding will ensure their work can continue over the next four years.

“These federal funds will help ensure that the University of Rochester can continue to be one of the most innovative and cutting-edge research institutions in the country,” said U.S. Senator Kirsten Gillibrand.

Strategic Plan

Mission

The CTSI develops, demonstrates and disseminates methods and approaches to advance translational research, by providing education and training, supporting transdisciplinary teams, improving quality and efficiency, and engaging community stake holders.

Vision

By 2020, the CTSI will be a replicable model environment for research across the translational spectrum from molecules to populations that is responsive to community priorities, conducted by transdisciplinary, patient- and community-engaged teams, and that improves population health.

Values

The CTSI shares the University of Rochester Medical Center's ICARE values: Integrity, Compassion, Accountability, Respect, and Excellence. We believe that exceptional patient care starts with exceptional research.

Integrity

The CTSI promotes research that is reproducible, community-engaged and compliant with rules and regulations.

Compassion

The CTSI manifests its compassion through our goal of improving population health and reducing health disparities in our communities.

Accountability

The CTSI meets the commitments it makes to funders and the community. We are accountable to the University, funding agencies, local and global communities, for whom we provide research and education programs. We are committed to developing metrics



of accountability consistent with these values.

Respect

The CTSI actively solicits community input to guide its work and acts upon that input. We respect the differing values of the communities we serve, students, researchers, patients, and community members. We are committed to the value of team science, which includes fostering a culture of transdisciplinary respect and active engagement with scientists of every background and perspective.

Excellence

The CTSI strives to be a national model for excellence in translational science and research education pro-

grams. We are dedicated to training and supporting researchers to enable them to achieve the highest quality of work in their fields. We are committed to excellence in translational research at a national level, balancing efficiency, integrity and timeliness.

Who We Are

The CTSI helps research teams produce results better, faster and cheaper, with the ultimate goal of improving the health of communities and populations. We link researchers with the connections, resources and education they need for success.

Education



The CTSI has an educational program for you, whether you are faculty, staff or a pre-doctoral student. Flagship programs include the KL2 Career Development Program for junior faculty, the PhD Program in Translational Biomedical Science, the Academic Research Track (ART) Program for medical students, and the Mentor Development Program for faculty mentors. There's more! Learn about all our programs at ctsi.urmc.edu.

Former KL2 Scholar Honored as Brilliant New Investigator

Feng (Vankee) Lin, PhD, RN, assistant professor of Nursing at the University of Rochester and past KL2 scholar, received the Brilliant New Investigator Award from the Council for the Advancement of Nursing Science (CANS) in 2016. The award recognizes early stage scientists who show extraordinary potential to develop sustained programs of research that will have a significant impact on the science and practice of nursing and health care.

Lin received a KL2 Mentored Career Development Award from the University of Rochester Clinical and Translational Science Institute in 2013 to examine how computer-based brain fitness activities may slow cognitive and functional decline in older adults with mild cognitive impairment, a precursor to Alzheimer's disease. Since, she has secured a \$2 million National Institute of Nursing Research grant to continue this research, and a \$421,000 grant from the National Institute on Aging to study fatigability among aging populations. She also recently received the University of Rochester's Valerie and Frank Furth Fund Award to support her investigation of "supernormals", older adults who have maintained their memory capacity substantially better than their peers.

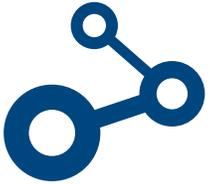
Lin currently carries joint appointments as an assistant professor in nursing, the Department of Psychiatry and the Department of Brain and Cognitive Science. She is also director of the CogT Laboratory, which focuses on preventing cognitive decline and promotes successful cognitive aging.

New Program: Research Methods Forum

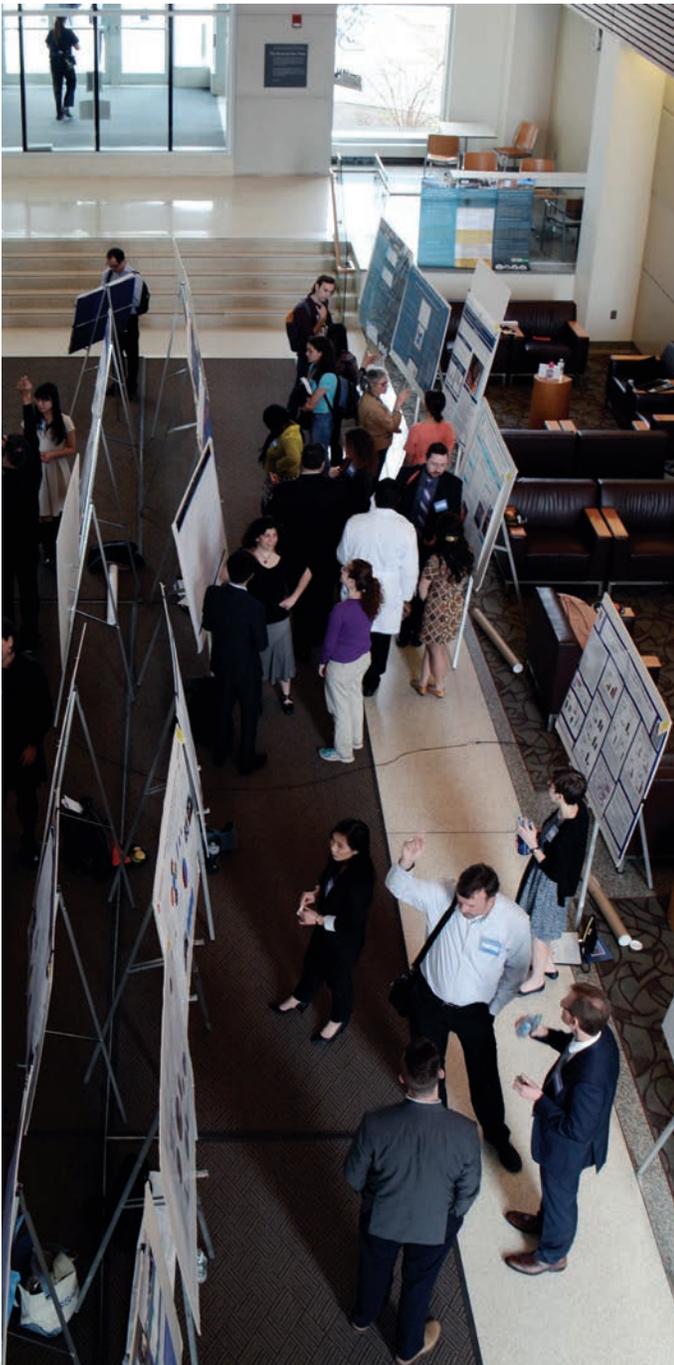
The Research Methods Forum, launched in May of 2017, provides an interactive setting for investigators to present new and developing research ideas to multidisciplinary experts in clinical research methods and potential collaborators, who will provide recommendations. Interested investigators have the opportunity to present their research proposals at an early stage of project development, and again when the research design is more advanced and the collaborative team is more established.



Connections



The CTSI can connect you with colleagues throughout the University, including the Center for Community Health, the Center for Human Experimental Therapeutics, the Center for Research Implementation and Translation, the Greater Rochester Practice-Based Research Network, and the UNYTE Translational Research Network.



Rochester Global Health Symposium & UNYTE Scientific Session

The Second Annual Rochester Global Health Symposium & UNYTE Scientific Session occurred April 21st, 2016. The symposium brought together leaders in global health research from Upstate New York and around the world to promote research collaboration, provide networking opportunities and help new researchers begin a career in global health.

The event was a collaboration between the Global Network, CDC-sponsored multi-institutional global health research network, and the CTSI-led UNYTE Translational Research Network. UNYTE hosts a series of semiannual scientific sessions intended to connect researchers, clinical leaders, and data scientists from across UNYTE institutions to spark interdisciplinary collaborations in practice-based research, clinical innovation, patient engagement, and research recruitment.

The one-day event included timely presentations on global health issues, a poster session, a student poster competition, and breakout sessions. Multiple networking opportunities gave participants a chance to share ideas one-on-one and connect with experts in the field.

Featured Topics included:

- Technology as a tool to address global health disparities
- Food security
- Zika virus and health diplomacy
- Mobile technologies
- Global cancer prevention and control
- Building partnerships in global health research
- Beginning a career in global health research

Connections

SCORE Half-Day Seminar: A Minds-On Practice

The Study Coordinators Organization for Research & Education (SCORE) recently held its 8th annual Half-Day Seminar. SCORE is a CTSI-sponsored network of study coordinators at the University. The group meets to share information, to collaborate to develop tools and practices, and to learn more about how to conduct human subjects research at the University.

This year, the seminar included lectures on self-determination theory, standard operating procedures, and mindful practice, and also focused on root cause analysis, a method of reviewing adverse events that occur in clinical research in order to prevent recurrence.

With recent changes in Food and Drug Administration guidelines for investigation of adverse events in clinical trials, some of the burden of root cause analysis has fallen to study coordinators and research nurses. So SCORE decided to include a hands-on and “minds-on” root cause analysis practice in breakout sessions this year – a first for the SCORE Half-Day Seminar.

The hands-on practice was kicked off with a lecture on root cause analysis by Michael Leonard MD, MS, associate professor of Pediatrics and associate chief quality officer for UR Medicine. During his lecture, Dr. Leonard and a group of actors introduced a hypothetical scenario of an adverse event in clinical research where key information was purposefully left out. In the scenario, a teenaged participant in a clinical trial for a depression medication was sent

to the emergency department after overdosing on the study drug.

Participants had the opportunity to gather more information by asking the actors questions prior to breaking into groups for discussions with trained facilitators. The seminar participants divided into six groups to review the facts and find areas or policies that could be changed to prevent this adverse event from happening again.

The presentation that followed the root cause analysis activity was an orientation to the development of Standard Operating Procedures (SOPs), which are a set detailed instructions for each process used in a clinical study. Root cause analysis often leads to development or modification of SOPs in order to prevent future adverse effects or breaches of protocol.

Closing the Half-Day, attendees participated in a mindfulness exercise guided by Ronald Epstein MD, professor of Family Medicine, Psychiatry and Oncology at URMC. Attendees were introduced to the concepts of mindfulness, to promote resilience and well-being in the workplace.

The seminar was well-attended with 123 participants from 9 institutions, with over 30 University of Rochester departments represented.



Resources



The CTSI offers a Pilot Study Program (1-year pilots for faculty and trainees, \$25,000 to \$50,000); the Incubator Program (2-year “super-pilots”, \$125,000/yr); Regulatory Support services, Informatics Consultations and the Research Help Desk.

Pilot Studies Program

The CTSI Pilot Studies Program provides seed funding for highly innovative translational and clinical research that addresses translational research questions, and provides insights generalizable to other projects. Research that moves new discoveries along the translational continuum to humans and the community is strongly encouraged. Clinical and community-based research, practice-based research, and health services research proposals are also encouraged. Priority will be given to multidisciplinary research teams, and to proposals with a substantial component of or impact on population health.

Investigator-initiated Pilot Studies for Faculty

Faculty awards lay the foundation to obtain subsequent extramural funding. The CTSI requires that faculty awardees demonstrate academic productivity through publication of the research. The award provides a maximum of \$50,000 for a period of one year.

Investigator-initiated Pilot Studies for Trainees

Trainee awards help awardees obtain the most prestigious fellowship possible following the project. The project should be part of a long-term plan to become an independent investigator. The award provides a maximum of \$25,000 for a period of one year.

UNYTE Translational Research Network Grants

UNYTE Translational Research Network awards stimulate new inter-institutional research collaborations. The most competitive proposals will involve an innovative, team-based health research project that reflects the particular strengths of UNYTE members and their institutions. The CTSI requires that faculty awardees demonstrate academic productivity through publication of the research. The award provides a maximum of \$50,000 for a period of one year.

Novel Biostatistical and Epidemiologic Methods (NBEM) Awards

Novel Biostatistical and Epidemiologic Methods awards support the development of novel biostatistical and epidemiologic methods that overcome specifically identified analytic limitations and significantly enhance the validity and accuracy, scope or speed of clinical or translational research. A maximum of \$35,000 will be awarded for a 1 year period. Strong proposals spanning two years will be considered on a case-by-case basis.

Incubator Program

The CTSI Incubator Program supports “super-pilot projects,” two years in duration, that are intended to accelerate innovative scientific discovery in the life sciences and public health, leading to new independently funded research programs. Each award is funded at a maximum level of \$125,000 per year for each of two years. Faculty from all UR schools are eligible to apply.

Like traditional program project grants, Incubator projects will consist of two or more individual pilot projects, led by collaborating investigators and linked by a scientific or clinical theme. The goal of the program is to identify research collaborations at the institution with tremendous potential to deliver a quantum advance in therapies, diagnostic techniques, or population and public health programs, accelerating scientific progress and leading to programmatic levels of extramural funding. An assigned CTSI project officer will serve as a link between funded investigators, the CTSI and other appropriate resources throughout the duration of the research project.

CTSI Consultations and Collaborations in Biomedical Informatics and Data Management

The CTSI provides consultations to help research teams plan informatics-related projects, and collaborates with teams to make use of biomedical informatics methods and resources to facilitate and expand the scope of their work. Available consultation types include data management, REDCap, Clinical data access and more.

Clinical Research Center

The Clinical Research Center (CRC) consists of dedicated space and skilled nursing staff that together support clinical research studies for investigators across URM. Since 1960, the CRC has been funded to provide the necessary infrastructure for investigators to conduct research studies. The facility provides an optimal setting for medical investigators to conduct safe, controlled, inpatient and outpatient studies of both children and adults. The center hosts both investigator-initiated and drug company-sponsored clinical trials, and is conveniently located on the ground floor of the medical center, with patient parking nearby.

Community Engagement Studio

Launched in February 2017, CTSI Community Engagement Studios offer an opportunity for community members to provide feedback to a researcher about research questions and methodology. The studio is a guided approach to patient and community engagement which allows researchers to obtain direct input from representative groups. Each studio is moderated by a neutral facilitator; community members typically respond to two to three focused questions regarding the research project. The CTSI has conducted two community engagement studios so far with great enthusiasm from the community and researchers and two more studios are planned for the near future.

Greater Rochester Practice-Based Research Network (GR-PBRN)

The Greater Rochester-PBRN (GR-PBRN) brings together primary care clinicians and researchers in a collaborative model designed to improve patient care and outcomes. We currently have 85 practices in our network, including 40 pediatric practices, 14 family medicine practices, 17 internal medicine practices, and 4 med/peds practices. Our member practices represent more than 200,000 adults (about 30% of Monroe County) and 150,000 children (80% of Monroe County). The CTSI offers consultation on conducting practice-based research and recruiting from primary care practices.

Kieburz Steps Down as CTSI Co-Director

Karl Kieburz, MD, MPH, co-director of the Clinical and Translational Science Institute, stepped down from that role at the beginning of the year, leaving the CTSI in the capable hands of his co-directors, Martin Zand MD, PhD, and Nancy Bennett MD. Kieburz, who has been with the University of Rochester Medical Center since 1985, was tapped to serve as CTSI director in September of 2013. He brought to that role a unique expertise in clinical networking as well as design and implementation of multi-site clinical trials. According to Kieburz, he decided to step down from this role to allow him to focus on his personal research interests. He has continued on as part-time faculty in the Department of Neurology and in the Center for Human Experimental Therapeutics and continues to be affiliated with the CTSI, but in an advisory capacity. "When I accepted the position as Director of the CTSI three years ago," said Kieburz, "my goal was to ensure that the institute's primary funding be renewed." With the successful renewal of the Clinical and Translational Science Award in August of 2016, Kieburz fulfilled that goal and felt it was time to hand the reigns over to Bennett and Zand who have both served as CTSI co-directors alongside Kieburz since the beginning of 2015. Bennett and Zand have taken on most of Kieburz' day-to-day duties and continue to lead the CTSI as a team. The CTSI thanks Kieburz for his years of leadership and wishes him the best!





The Clinical and Translational Science Institute is committed to diversity and inclusion in workforce development, community engagement, and research participant recruitment.

John Cullen, PhD, joined the CTSI in 2016 to bring a renewed focus on diversity and inclusion. He is tasked with narrowing some of the gaps that can affect and sometimes stymie medical research. He is also looking at ways that the medical center can encourage diversity among staff and faculty.



“Studies have shown that a more diverse workforce is a more productive workforce,” said Cullen. “You get a wider array of ideas, which leads to better and quicker advances.”

The former chair of the University’s Pride Alliance, Cullen became interested in diversity and inclusion early in his career and has extensive experience working with both the Office of Faculty Development and Diversity and the Office for Inclusion and Culture Development. In recent years, he received his graduate certificate in LGBT health policy and practice, and began working at the Susan B. Anthony Center, where he serves as coordinator of outreach and works to translate research into policy, with a focus on healthcare disparities and vulnerable populations.

Previously, he spent 15 years in the Department of Surgery, conducting both basic science and clinical research into how alcohol consumption affects cardiovascular disease and trauma.

Within the CTSI, Cullen hopes to spread the message among researchers that focusing on diversity – specifically studying diverse populations or ensuring that a study cohort is adequately diverse – is a worthwhile endeavor. On a broad level, Cullen will support the University’s strategic plan, which includes a sustained effort to promote diversity and inclusion by developing a central infrastructure that enables consideration of issues of diversity in workforce development and trainee education. A more diverse culture helps with recruitment and retention, as well as scientific impact.



The Saunders Research Building

The development of the University of Rochester Clinical and Translational Science Institute was also the catalyst that led to the construction of the Saunders Research Building, which was completed in 2011 with \$50 million New York State funding. The 200,000-square-foot space was built to provide a home for clinical and translational research. The building was named in recognition of E. Phillip Saunders, whose long-standing commitment to medical research at the URMC and generous \$10 million gift to the CTSI has been instrumental in fostering muscular dystrophy, cancer, and translational biomedical research.



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Clinical and Translational Science Institute
Saunders Research Building, Suite 1.200
265 Crittenden Blvd, | Rochester, NY 14642-0708
(585) 275-0653 | ctsi.urmc.edu |  